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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/817,595	04/22/1997	ANGELA TURIANO	MARGI-15	8416

7590 11/03/2003

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/03/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/817,595

Applicant(s)

TURIANO, ANGELA

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/7/2006 has been entered.

2. Claims 25-39 are pending and examined on the merits.

New Arguments

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 25-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartorelli *et al* (WO 92/10197). Claims are drawn to a kit comprising at least two containers, each comprising an extract or MHC molecule from an animal tissue, serum, or cell source wherein extracts comprise allogeneic or xenogeneic molecules; are prepared by homogenization in NP-40, treating with acid, or treating with preteolytic enzyme, wherein each container comprises a different tissue, serum or cell source that is derived from the same animal, same species, or different species (claim 25); wherein

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the extracts are from different species (claim 26); wherein the said animal is human (claim 27); wherein the said tissue, serum, or cell source is goat, calf, or pig liver or bovine red blood cell (claim 28); wherein the MHC molecules have a molecular weight above 10000 daltons (claim 29). The claims are also drawn to a kit comprising at least two containers, each comprising an MHC molecule from an animal tissue, serum, or cell source wherein extracts comprise allogeneic or xenogeneic molecules; are prepared by homogenization in NP-40, treating with acid, or treating with preteolytic enzyme, wherein each container comprises a different tissue, serum or cell source that is derived from the same animal, same species, or different species (claim 39). The claims are further drawn to a method of preparing the said kit (claim 30-33), and a method of treating carcinoma using the said kit (claim 34-38).

Bartorelli *et al*/ disclose a substance that is prepared in a manner that is identical to that instantly claimed, wherein a tissue source (namely goat or sheep) is homogenized and treated with an acid to extract a substance referred to as LGE. Because the extraction methods appear to be identical and the source of the substance is the same as that instantly claimed, in the absence of evidence to the contrary, the LGE disclosed is an MHC molecule. Bartorelli *et al*/ further disclose the characterization of the LGE by PAGE analysis and discover protein migration correlating the molecular weights greater than 10,000 Daltons (see page 5 and 6). It is also disclosed that the LGE substance can be used for the treatment of different types of tumors (see page 23, table 4). It is further disclosed that the LGE substance can be prepared through either homogenization and acid digestion or by using detergents extractions methods common

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to those of skill in the art (see page 3). Although the LGE product is not characterized as being an MHC molecule or as being separated into different containers, it is an obvious combination to one of ordinary skill in the art.

It would have been *prima facie* obvious to one of skill in the art at the time the invention was made to combine MHC molecules derived from different tissue, serum or cell sources into two separate containers. One of skill would have been motivated to do so because the extraction of MHC molecules from different tissue sources (i.e. different goat or sheeps) vary from source to source and would thus require the separation of extracts into easily distinguishable batches. Furthermore, one of ordinary skill in the art would have been motivated to use the combination of the tissue extracts for the treatment of cancers because Bartorelli *et al* taught that the administration of the "LGE substance", which appears to be the same as MHC molecules, was effective in the treatment of a varying types of cancer. Therefore, the skilled artisan would have found reasonable expectation of success in using the combination of different sources because it was taught that the administration of the "LGE substance" was able to induce an immune response to the tumor cells.

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All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 34.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen

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October 29, 2003

A handwritten signature in black ink, appearing to read "Christopher Yaen", is written over the typed name and date.